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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,758

06/18/2007

Edward G. Shifrin

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EXAMINER

CHUKWURAH, NATHANIEL C

ART UNIT

PAPER NUMBER

3721

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,758	<b>Applicant(s)</b> SHIFRIN ET AL.	
	<b>Examiner</b> NATHANIEL C. CHUKWURAH	<b>Art Unit</b> 3721	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/22/2006</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. Applicant's election without traverse of claim 10-27 in the reply filed on 2/9/2009 is acknowledged.

#### ***Information Disclosure Statement***

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 12 and 13 recites "means for setting apart the ends of the latter" in line 8.

It is unclear as to what element is referred to as the latter.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 10, 12-15, 17, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Perouse et al. (US 5,346,115).

With regard to claim 10, Perouse discloses a surgical staple inserter comprising:

a tubular body (22) considered to rigid and flexible, configured for positioning within a blood vessel, a substantially cylindrical head (225) disposed at the free end of this tubular body and having an inner axial cavity, a die (40) and die lid (82, 207) being rigidly mounted at the proximal end of this head, the die and die lid being coaxial with this head and with one another; a die (staple holder 32) grooved for U-shaped staples (94), shaped substantially as a barrel, a substantially V-shaped means (collar piece 112) for setting apart the ends of said U-shaped staples, the die lid (82, 207) has a through axial hole, means (24 duct) for retaining the free ends of U-shaped staples and means (102 groove) for separating from the stapler the middles of these U-shaped staples at the end of their working stroke, these means being disposed near the points of intersection of the radial slots with the distal end face and the cylindrical generatrix of the die lid (82, 207); a control mechanism (201, 203) disposed at the end of the tubular body, a retaining handle (201) extending from this distal end sidewise at a certain angle, from about 30 degrees to about 90 degrees as show in Fig. 22, and a control lever (203) pivotally mounted on said

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retaining handle; a pressure rod (309) considered to be rigid and flexible, located within the hollow body, means (246) for transmitting axial force from the pressure rod to the fastener means (94), substantially U-shaped staples, and for transforming this axial force into radial forces applied to each of these U-shaped staples, a means (206) considered to be for temporary fixation on the stapler body of delivered intravascular devices.

With regard to claim 12, Prouse shows the die (22) and the claimed features of the die as shown in Figures 7 and 10.

With regard to claim 13, Prouse shows the die (22) for receiving staples (94), radial slots (95), and die lid-recesses with grooves (100, 134) for receiving fastener means (94), substantially U-shaped staples, the die (22 Fig. 6) is shaped as a barrel with a substantially cylindrical generatrix and inner axial cavity open on the side of the distal end of this barrel and terminating in a bottom at the proximal end of the barrel (Fig. 4), means (102 groove) for setting apart the ends of the fastener, the recesses with grooves (100, 134) have substantially different depths relative to the end face of the die bottom and are coaxial with the radial slots.

With regard to claim 14, Prouse shows recesses with grooves (100, 134) considered to have at least two different depths relative to the end face of the die bottom, and alternating with one another.

With regard to claim 15, Prouse shows fastener means (94) formed substantially as U-shaped staples and located radially in the grooves (100) of the stapler die (40) to extend radially from the grooves due to radial forces, the free ends of the U-shaped means (94) being disposed on both sides of the means (102 groove) for setting apart the ends of these fastener means located

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along the axes of the grooves, immediately adjacent to the cylindrical generatrix of the die and being substantially V-shaped ( Fig. 10).

With regard to claim 17, Perouse shows means (102 groove) for setting apart the ends of the fastener means (94).

With regard to claim 19, Perouse shows the die lid is provided with means (102 groove) considered to be for separating staples.

With regard to claim 21, Perouse shows a pressure rod (205) having a longitudinal axis, substantially conical proximal end as shown in Figure 1, distal end and (hoop end) considered to be thrust collar near the distal end (Fig. 14), this pressure rod is rigid in longitudinal direction and considered to be flexible in lateral direction to allow for repositioning, the pressure rod being spring-loaded (310), operatively associated by its distal end with the control lever (203) and capable of reciprocation by the distal end-within the hollow body of the control mechanism, and by the substantially conical proximal end-within the inner axial cavity of the die.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 18 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perouse et al.

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With regard to claim 18, Perouse die and die lid provided with means (wall) for retaining the free ends of the staple, and Perouse to a degree does not show the staple retaining means containing torsion spring elements disposed near the points of intersection of the radial slots with the distal end face and the cylindrical generatrix of this die lid.

Applicant has not disclosed that having a torsion spring elements to retain the staple free ends solves any states problem or that it provides advantage, and it appears that the wall of the die and lid retains the staple free end equally well. However, it would have been obvious to one skilled in the art to modify the Perouse's die and lid to include the spring element in order to retain the staple free.

With regard to claims 22 and 23, Perouse shows a pressure rod (309) having a longitudinal axis, substantially conical proximal end as shown in Figure 23 with a cone vertex angle to the degree that it does not show specific vertex angle from about 10 degrees to about 20 degrees or from about 3 to about 35 degrees. Angles in the range above are necessary to provide a cam effect in order to outwardly push the staple pusher to fasten the staples.

However, it would have been obvious to one skilled in the art to modify the Perouse's cone vertex angle from about 10 degrees to about 20 degrees or from about 3 to about 35 degrees for the purpose of providing a cam effect to outwardly push the staple pusher to fasten the staples.

10. Claims 11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perouse et al. (US 5,346,115) in view of Huxel et al. (US 6,503,259).

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With regard to claim 11, Perouse discloses the claimed cylindrical hollow body of the control mechanism (201, 203) provided with a swing lock (204) and control lever (203) pivotally mounted on the retaining handle, the control lever (203) has a pressure end (222) movably mounted within the hollow body in the clearance between the spring-loaded end of the pressure rod (309). Perouse shows the claimed elements to the degree that it does not show an adjusting screw coaxial with this pressure rod.

Huxel teaches adjusting screw (92) coaxial with this pressure rod (72) for the purpose of adjusting the position of the actuator rod (72). In view of the teaching of Huxel, it would have been obvious to one skilled in the art to modify Perouse's stapler by providing the adjusting screw in order to adjusting the position of the pressure rod.

With regard to claim 27, Perouse shows means (206) for temporary fixation on the stapler body of delivered intravascular devices, substantially grafts or stent-grafts (26), and an adjusting screw as shown in Huxel with a head considered to be thrust head located in the distal part of said body of the control mechanism.

11. Claims 16 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perouse et al. (US 5,346,115) in view of Dakov (US 5,720,755).

With regard to claim 16, Perouse discloses the claimed subject matter to the degree that it does not show grooves, substantially V-shaped, with lateral guiding faces which are substantially curvilinear, concave and diverging from one another in direction from the center of the die.

Dakov teaches shaped die as shown in the Figures including grooves considered to be substantially V-shaped as shown in Figure 14A and 14B with lateral guiding faces which are



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substantially curvilinear, concave and diverging from one another in direction from the center of the die. In view of the teaching Dakov, it would have been obvious to one skilled in the art to modify Perouse by providing the die with grooves having lateral guiding faces which are substantially curvilinear, concave and diverging from one another in order to accommodate changing lumen.

With regard to claim 24, Perouse discloses the claimed subject matter to the degree that it does not show means (curved L-shaped levers) for transmitting axial force from the pressure rod to the fastener means.

Dakov teaches curved L-shaped levers (Fig 13 C and 13D) for transmitting axial force from the pressure rod to the fastener means. In view of the teaching Dakov, it would have been obvious to one skilled in the art to modify Perouse by providing the curved L-shaped levers for purpose of for transmitting axial force from the pressure rod to the fastener means.

With regard to claim 25, modified Perouse shows curved L-shaped levers (Fig. 13C Dakov) pivotally mounted by the ends of their long arms on a ring located within the inner axial cavity of the die.

With regard to claim 26, modified Perouse includes die, die lid and staples, form in combination a single set of the stapler actuator (Dakov Figs. 12A-18 B, which is configured to be removed from the stapler body and then replaced by other, similar interchangeable sets.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perouse et al. in view of Irion (US 2002/0007110).

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With regard to claim 20, Prouse discloses the subject matter to the degree that it does not show the die lid made of a transparent material for checking the state of substantially U-shaped staples. Irion teaches that it is well known in the art to provide a transparent end effector/trocar tube for the purpose of viewing the operating condition of the surgical stapler.

Therefore, it would have been obvious to one skilled in the art to modify the die lid of Prouse to include transparent material for the purpose of viewing the operating condition of the surgical stapler.

### ***Conclusion***

13. Refer to attachment for notice of references cited and recommended for consideration based on their disclosure of limitations of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHANIEL C. CHUKWURAH whose telephone number is (571)272-4457. The examiner can normally be reached on M-F 8:00AM-4:30PM.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on (571) 272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathaniel C. Chukwurah/  
Examiner, Art Unit 3721

/Rinaldi I Rada/  
Supervisory Patent Examiner, Art Unit 3721

4/21/2009

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